

121



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,949	02/15/2001	Arthur Campbell	PD-0387	4193
23608	7590	06/17/2004	EXAMINER	
MEDTRONIC MINIMED INC.			LAM, ANN Y	
18000 DEVONSHIRE STREET			ART UNIT	
NORTHRIDGE, CA 91325-1219			PAPER NUMBER	

1641

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/784,949		CAMPBELL ET AL.	
	Examiner		Art Unit	
	Ann Y. Lam		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/5/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed March 5, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 24-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 (line 4), 42 (line 3) and 43 (line 3) recite "a housing sized to be carried by the user and fit in a clothing pocket". The limitation relates the size of the housing to the size of a clothing pocket. Since the size of a clothing pocket can be of any various dimension, the size of the clothing pocket is indefinite; and thus the size of the housing is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-10, 12 and 15-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Henne, 4,212,738.

Peterson discloses the invention substantially as claimed.

More specifically, as to claims 1, 42, and 43, Peterson et al. discloses a drive mechanism (72) that forces the fluid out of a reservoir; an input device, see column 9, line 58; a processor (504); a display (see column 5, line 45 for example) that receives information from the processor and visually displays one or more screens containing the information; wherein at least one of the one or more screens includes a menu with at least two menu items, wherein the input device is used to select one menu item from amongst the at least two menu items, and wherein selection of one of the at least two menu items causes the display to show at least another one of the one or more screens that is a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated with the selected menu item, and wherein the input device is used to program the plurality of control parameters associated with the selected menu item from the set screen, see

Art Unit: 1641

column 8, line 67 – column 9, line 3, and column 9, lines 11-29, and column 9, line 58 – column 10, line 3, and column 11, lines 28-39.

As to claims 3, 18, 39 and 40, the system includes a means (504) to store a maximum bolus that is programmable using the input device, see column 17, lines 29-33, and column 22, line 35, wherein the maximum bolus limits the maximum units of fluid that can be delivered in a single bolus.

As to claims 39 and 40, the bolus is considered to be an express bolus or an easy bolus.

As to claims 4 and 17, the system includes a means to store a maximum basal rate as claimed, see column 17, lines 60-63.

As to claims 5, 47, 48, 49, 50, the system includes a means to store one or more basal profiles as claimed, see column 17, lines 60-63.

As to claim 6, the system includes one or more alarm types as claimed, see column 21, lines 15-19.

As to claims 7 and 20, the system includes a means (504) to store an insulin type.

As to claims 8 and 21, the system includes a means (504) to store a reservoir type as claimed.

As to claims 9, 10, selection of one of the two menu items causes the infusion system to reset the control parameters to factory default values, see column 33, lines 16-19.

As to claim 12, at least one of the menu items causes the drive mechanism (72) to reverse direction.

As to claims 15 and 41 the screen is considered to be a status screen.

As to claims 16 and 19, the one or more screens is considered to include one or more set or select screens that is a set screen including a single control parameter associated with the selected menu item, and wherein the input device is used to program the single control parameter associated with the selected menu item from the set screen, see column 9, line 15-16.

As to claim 22, the one or more select screens is considered to include a screen to select a language.

As to claims 23 and 24, a housing, infusion set and tubing as claimed is disclosed, see column 2, lines 57-62.

As to claims 25 and 26, a manual prime or a fixed prime may be used to fill the tubing with fluid from the reservoir, see column 11, lines 37-39.

As to claim 27, the information is shown on the display screen to guide an individual through the steps to prime the infusion system as claimed, see column 11, lines 28-38.

As to claim 28, one of the at least two menu items is highlight when the menu is displayed, see column 11, lines 28-32.

As to claim 29, the one of at least two menu items that is highlighted when the menu is displayed is considered dependent on a function that the infusion system is performing when the menu is displayed as claimed, see column 11, lines 28-39.

As to claim 30, the system further includes a communication device for receiving communications from an external device to control the drive mechanism, see column 13, lines 38-41.

As to claim 31, selection of at least one of the at least two menu items causes the display to show a screen that allows an individual to signify the identity of a device, which thereby configures the infusion system to accept communication from the device, see column 13, lines 55-64.

As to claim 32, the input device includes a keypad, see column 9, line 49.

As to claim 33, when the infusion system is suspended from delivering fluid, fluid delivery is resumable with two or less keystrokes independent of the screen being displayed, see column 32, lines 40-50.

As to claim 34, the ENTER/CLEAR, see column 9, line 18, is equivalent to an ACT key as claimed.

As to claims 35 and 36, the ENTER/CLEAR key, see column 9, line 18, is equivalent to an Esc key as claimed.

As to claims 37 and 38 a single keystroke is used to exit a Blank Screen and display at least one other screen, such as a Main Menu screen, see column 9, line 49.

As to claim 44, the screen is considered to select a therapy.

As to claim 45, the input device is considered to include soft keys.

As to claim 46, the screen is considered to be a confirmation screen.

As to claims 51-54, the menu items include square wave bolus or dual wave bolus as claimed, see column 9, lines 30-45.

Peterson teaches that the apparatus is for kidney dialysis. However, Peterson does not teach that the housing is sized to fit in a clothing pocket.

Henne also teaches an apparatus for kidney dialysis, and discloses that the artificial kidney is capable of being work directly on the body of the patient. Thus, Henne teaches an apparatus for kidney dialysis that is sized to fit in a clothing pocket. It would have been obvious to form the Peterson apparatus for kidney dialysis in a small size to be worn on the body of the patient as would be desirable for portable use as taught by Henne.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Henne, 4,212,738, as applied to claim 1 above, and further in view of DeLaHuerga, 6,408,330.

Peterson in view of Henne discloses the invention substantially as claimed, except for the processor running energy management software that changes the display to a Blank Screen after a Time-Out delay has expired.

DeLaHuerga discloses a drive mechanism, see column 17, line 51, an input device, a processor (194), a screen (523) with a menu, see column 29, lines 62-64, as claimed, wherein the processor runs energy management software that changes the display to a Blank Screen after a Time-Out delay has expired, see column 25, lines 22-34, the steps being part of a mechanism that allows a user's access to the computer system to be restricted while logged off and enlarged while logged on, see column 25, lines 22-43 and particularly lines 44-46. It would have been obvious to provide this

feature in the Peterson-Henne device as part of a mechanism that is desirable for limiting access to a computer while logged off as taught by DeLaHueraga.

3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Henne, 4,212,738, as applied to claim 1 above, and further in view of Say et al., 6,175,752.

Peterson in view of Henne discloses the invention substantially as claimed, see above, except for the alarm intensity changing with time.

Say et al. discloses a drive mechanism (260), an input device (162), a processor, a screen and menu, see column 53, lines 226-27, as claimed. As to claim 11, the system includes an alarm wherein the alarm intensity changes with time, see column 46, lines 9-23. It would have been obvious to provide in the Peterson-Henne device an alarm that changes intensity with time as would be desirable for an alarm as taught by Say.

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Henne, 4,212,738, as applied to claim 1 above, and further in view of Benkowski et al., 6,183,412.

Peterson in view of Henne discloses the invention substantially as claimed, see above, except for the system performing a selftest.

Benkowski et al. discloses a drive mechanism (12), a processor (80), an input device, a screen and menu, see column 12, lines 38-4, as claimed. As to claim 13, selection of at least one of the at least two menu items causes the infusion system to

begin a selftest to check components of the controller module, see column 5, lines 51-52. It would have been obvious to provide a menu that causes the Peterson-Henne system to perform a selftest as would be desirable to check components of a controller module as taught by Benkowski.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Henne, 4,212,738, as applied to claim 1 above, and further in view of Havel, 5,003,298.

Peterson in view of Henne discloses the invention substantially as claimed, see above, except for a numeric value displayed on the screen wherein a number to the right of a decimal point is formatted differently than a number to the left of the decimal point.

Havel discloses a display wherein the digits that precede the decimal point are illuminated in a first color, and digits that follow the decimal point are in a second color, to more effectively emphasize the position of the decimal point, see column 1, lines 47-52, and column 3, lines 51-58. The number to the right of the decimal point is considered to be formatted differently than a number to the left of the decimal point. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide in the Peterson-Henne system the format for the digits to the right and left of a decimal point as taught by Havel in order to emphasize the position of the decimal point for easier reading.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

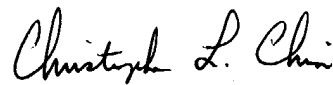
Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.




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